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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,238	09/26/2001	Kristin Verschueren	4232.1US	1860
24247	7590	07/06/2004	EXAMINER	
TRASK BRITT			CARLSON, KAREN C	
P.O. BOX 2550			ART UNIT	PAPER NUMBER
SALT LAKE CITY, UT 84110			1653	

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/964,238

**Applicant(s)**

VERSCHUEREN ET AL.

**Examiner**

Karen Cochran Carlson, Ph.D.

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,8,10,18,22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) 1,18 and 22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3,8,10,21 and 24-26 is/are allowed.
- 6) ☒ Claim(s) 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/449285.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The Office Action is in response to the paper filed May 21, 2004.

Claims 4-7, 9, 11-17, 19, 20, and 23 have been canceled. Claims 1, 18 and 22 have been withdrawn from further consideration by the Examiner because these Claims are drawn to non-elected inventions. Claims 2, 3, 8, 10, 21, and new Claims 24-26 are currently under examination.

Priority is set to June 2, 1997.

### **Withdrawal of Objections and Rejections**

The objection to the disclosure is withdrawn.

The rejection of Claims 2, 3, 8, and 21 under 35 U.S.C. 101 is withdrawn.

The rejection of Claims 2, 3, 8, and 10 under 35 U.S.C. 112, second paragraph, is withdrawn.

The rejection of Claims 2, 3, 8, and 10 under 35 U.S.C. 112, first paragraph, is withdrawn.

### **Maintenance of Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

On page 3 of the specification, Applicants admit that Zhang et al., Laguna et al., and Chen et al. are all prior art against their broadly claimed invention. Therefore, the following rejections are being made:

Claim 2 is again rejected under 35 U.S.C. 102(a) as being anticipated by Zhang et al. (Sept. 12, 1996; Nature 383(168-172).

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Zhang et al. teach hMAD-4 interacts with hMAD-3. Therefore, hMAD4 is a SMAD interacting protein because it interacts with hMAD-3. The reverse is also true, that is, hMAD-3 is a SMAD interacting protein because it interacts with hMAD-4.

Claim 2 is again rejected under 35 U.S.C. 102(a) as being anticipated by Laguna et al. (Oct. 31, 1996; Nature 383:832-836).

Laguna et al. teach that SMAD-4 (DPC4) forms a complex with SMAD-1 and with SMAD-2 and is essential for SMAD-1 and SMAD-2 function. Therefore, SMAD4 is a SMAD interacting protein because it interacts with SMAD-1 and SMAD-2. The reverse is also true, that is, SMAD-1 and SMAD-2 are SMAD interacting proteins because they interact with SMAD-4.

Claims 2 is rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al. (Oct. 24, 1996; Nature 383:691-696).

Chen et al. teach that XMAP2 (SMAD-2) forms a complex with forkhead activin signal transducer-1 (FAST-1). Therefore, FAST-1 is a SMAD interacting protein because it interacts with SMAD-2.

Applicants urge that they have not admitted that Zhang et al., Laguna et al., or Chen et al. is prior art against their invention. This argument is not persuasive because at page 3 such is admitted.

Applicants argue that the claims do not recite that the SMAD interacting protein binds to the C-terminal domain of a SMAD, and thus the references are not prior art even if they constitute prior art. This argument is not persuasive because binding the C-terminal domain of a SMAD is an inherent property of the SMADS, and Applicants admit such in the specification.

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There is sufficient evidence that the product disclosed by the reference is Applicants' product, and the burden is shifted to Applicants to distinguish the two. See *In re Best*, 195 USPQ 430 and *Ex Parte Gray* 10 USPQ 2d 1922, 1923.

Claims 3, 8, 10, 21, and 24-26 are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

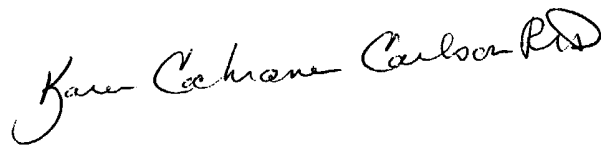
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink that reads "Karen Cochrane Carlson Ph.D." The signature is written in a cursive, flowing style.

KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER